UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

September 23, 2008

DP Barcode:	D354468
MRID:	Copy of 429385-03
Subject::	*Valvtect Marine Heavy Duty Premium Diesel with Bioguard Microbiocide*
Reg. No.	EPA REG. # 60061-REI
Document Type:	Product Chemistry Review
End-Use Product [X]	
Ingredients (PC Codes)	100801, 100802
CAS Numbers:	NA (Mixture)
Submitter:	Kop-Coat, Inc. .
Guidelines:	830.1550
Commodities:	Amended Confidential Statements of Formula
Reviewer::	Nancy G. Whyte Microbiologist, Special Assistant Product Science Branch
Organization:	Antimicrobials Division
Approver:	
Comment:	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION,
PESTICIDES AND
TOXIC SUBSTANCES

To: PM/PM Reviewer: Marshall Swindell/Martha Terry
PM Team #33

From: Nancy G. Whyte, Microbiologist/Special Assistant
Product Science Branch
Antimicrobial Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

Applicant: Kop-Coat Inc.

Action code: A531

Due date: September 25, 2008

Product Formulation:

Active Ingredient(s):	**%/wt**
4-(2-Nitrobutyl) morpholine	21.86%
4,4'-(2-ethyl-2-nitrotrimethylene) dimorpholine	1.33%
Inert Ingredients	76.81%
Total	100.00%

Background:

Kop-Coat Inc. has submitted a re-application for registration of a new end-use product, *ValvTect Marine Heavy Duty Premium Diesel with Bioguard Microbiocide*. This product is a multifunctional diesel fuel additive that prevents bacterial growth. The applicant provided a Confidential Statement of Formula (CSF) for the basic formulation (dated June 17, 2008). The product is produced by a non-integrated system. The registered product, [redacted] is the source of the two active ingredients. Submitted as additional material is MRID #429385-03 containing a discussion of the analytical method used to determine the amount of active ingredient in the final product. According to a statement in this document the information does not meet the standards of Good Laboratory Practices, and is included as "a discussion, not a laboratory study".

Note: The applicant's letter to EPA (dated February 12, 2008) states that the product, *ValvTect Marine Heavy Duty Premium Diesel with Bioguard Microbiocide*, is substan-

Product ingredient source information may be entitled to confidential treatment

tially similar to the EPA-registered product, *ValvTect Marine Premium Diesel with Bioguard Additive* (EPA Reg. No. 60061-124).

Findings:

1. A number of inert ingredients in the formulation have not been approved for use in pesticides, and contain several components, some of which are listed in the Agency's Inerts electronic database, and others which are not. The registrant, at the Agency's request, has submitted additional information about the ingredients, but this information does not contain the amount of each component in the ingredient, and therefore is not acceptable. In other cases, the CAS numbers of one or more of the components are not listed in the database. For some of the ingredients the information is deficient for both of these reasons. See Confidential Attachment for listing of the unapproved ingredients.

2. If the registrant wants to continue to use the ingredients listed in the Confidential Statement of Formula, the supplier of the ingredient must submit directly to the Agency the following information:

   a) The trade name/chemical name of the ingredient,

   b) The CAS number of each of the chemicals/components in the ingredient,

   c) The amount of each component in the ingredient. The total amount in the ingredient must equal 100%.

   d) This information must be sent directly to the Agency by some secure overnight service delivery to the following address:

      Marshall Swindell, Product Manager Team 33
      Potomac One Building
      Rm-8828, MS 7510P
      US Environmental Protection Agency,
      2777 S. Potomac Drive
      Arlington, VA 22202

2. The information submitted to satisfy deficiencies noted in the previous review of this product has been reviewed and added to the product chemistry files. This includes the following required Series Guidelines: Oxidation/Reduction (630.6314), Explodability (830.6316), Miscibility (830.6319), a 3-month preliminary Storage Stability and Corrosion Characteristics studies (830.6317 and .6320), and Dielectric Breakdown Voltage.(830.6321).

3. The report of the analytical method contained in MRID 429385-03 was dated September 17, 1993, and as noted above, was not conducted using Good Laboratory Practices. This is not acceptable as a certification for the amount of active ingredient in the product for which registration approval is requested.

4. The printed label ingredients statement does not agree with the amounts of active ingredients listed on the Confidential Statement of Formula. The two must list identical amounts. (It may be that the label obtained from the files was not the most

recent one, but there was not a label included in the data package when received).

Conclusions:

1. Until such time all the ingredients have been cleared for use in pesticides, and Pesticide Chemical codes have been assigned to each, the Confidential Statement of Formula, dated June 17, 2008, is not acceptable to the Agency.

2. An analytical method which certifies the amount of active ingredient in the product must be conducted using Good Laboratory Practices (GLP) as a laboratory study, and not as a "discussion". Any test results which were obtained from non-GLP testing must be fully described, with an explanation of why the testing was conducted, and how the deviation differs from GLP standards required by the Agency in 830 Series Guidelines.

3. The registrant must submit a product label for review that lists the same nominal concentration amount of active ingredients as those listed on the Confidential Statement of Formula.

4. Until such time as the above information is received, reviewed, and approved by the Agency, this product is not approved for registration.

CONFIDENTIAL ATTACHMENT

The following inert ingredients listed as components in this product have not currently been approved for use in pesticides.

[redacted]

Inert ingredient information may be entitled to confidential treatment